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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,515	12/07/2004	Kyl L. Smith	681132-2US	2543

570 7590 06/24/2009

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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,515	SMITH, KYL L.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-8, and the species election disclosed as Claim 2, in the reply filed on July 27, 2007 is acknowledged. While Applicant's response is not fully compliant, the Examiner agrees to examine all of the species recited in the claims. And, therefore the requirement for species of election as set forth in the previous Office action is hereby withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCleary (A*) in view of Davis et al. (U), Singh et al. (Singh, H. K. et al. Indian Journal of Pharmacology, 1997; 29: S359-S365. Neuropsychopharmacological effects of the Ayurvedic nootropic *Bacopa monniera* Linn. (Brahmi)) and Ikeguchi et al. (A*)

Applicant claims a composition for enhanced mental function, wherein the composition comprises: a. vitamin B12 on ion exchange resin; b. phosphatidyl serine (PS); c. dimethyl-aminoethanol (DMAE); d. docosahexaenoic acid (DHA); e. L-

pyroglutamic acid; and herbal extracts from *Bacopa monniera*. Applicant further claims the composition of claim 1 further comprising at least one antioxidant complex selected from the group consisting of Vitamin A, Vitamin E, Vitamin C and proanthocyanidin. Applicant further claims the composition of claim 2 wherein the antioxidant is proanthocyanidin that is derived from grape or *Vitis vinifera* seed. Applicant further claims the composition of claim 1 further comprising at least one mineral complex selected from the group consisting of calcium, copper, iron, iodine, lithium, magnesium, manganese, potassium, vanadium and zinc. Applicant further claims the composition of claim 1 wherein the composition further comprises at least one B-complex Vitamin selected from the group consisting of Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5 and Vitamin B6.

McCleary teaches a composition for enhanced mental function comprising vitamin B12 (A); phosphatidyl serine (b); dimethyl-aminoethanol (c); docosahexenoic acid (d); antioxidants, including Vitamin E, Vitamin C and proanthocyanidins, namely resveratrol, an antioxidant derived from grape or *Vitis vinifera* seed (which meets the limitations of Claims 2 and 3); at least one mineral complex, including magnesium, potassium and zinc (which meets the limitations of Claim 4); at least one B-complex Vitamin, including Vitamin B1 (thiamine), Vitamin B2 (riboflavin), Vitamin B3 (niacin) and Vitamin B5 (pantothenic acid) (which meets the limitation of Claim 7); and, further comprising an herbal extract wherein the herb is *Vica minor* or *Huperzia serrata*, including Vinpocetine (an herbal extract obtained from *Vica minor*) and Huperzine A (an herbal extract obtained from *Huperzia serrata*) (which meet the limitations of Claim 8).

The teachings of McCleary, as set forth above, do not specifically teach the vitamin B12 constituent as vitamin B12 on ion exchange resin.

Davis teaches that serum levels of vitamin B12 are elevated more effectively by oral vitamin bound to an ion-exchange than by free vitamin because the resin-bound form prevents degradation of the drug in the stomach. Thus, it was known in the art at the time of the invention that vitamin B12 on ion exchange resin was an effective vehicle for increased absorption of oral vitamin B12. Therefore, an artisan of ordinary skill would have had a reasonable expectation that using the resin-bound vitamin B12 of Davis in the making of the composition taught by McCleary would be a success. This reasonable expectation of success would have motivated the artisan to provide the vitamin B12 disclosed in the composition taught by McCleary as a resin-bound vitamin B12 as disclosed by Davis because to do so would ensure the best possibility for enhanced absorption and increased circulation in the blood of vitamin B12.

The combined references of McCleary and Davis are set forth above. The combined references teach the claimed invention except for L-pyroglutamic acid and herbal extracts from *Bacopa monniera*. However, it would have been obvious to one ordinary skill in the art to add the claim-designated ingredients to the composition taught by the combined references to provide the claimed invention because at the time the invention was made Ikeguchi taught that 2-pyrroidone-5-carboxylic acid (also known in the art as L-pyroglutamic acid) was useful in the treatment of mental disorders, such as dementia and amnesia; and, Singh taught that compositions comprising an ethanolic extract from *Bacopa monniera* augmented cognitive function and mental retention

capacity. Since the L-pyroglutamic acid taught by Ikeguchi; and, the *Bacopa monniera* extract taught by Singh yielded beneficial results in the enhancement of mental function, the artisan of ordinary skill would have had a reasonable expectation that the addition of the claim-designated ingredients to the composition taught by the combined references of McCleary and Davis would be a success. This reasonable expectation of success would have motivated the artisan to add the L-pyroglutamic of Ikeguchi and the *Bacopa monniera* of Singh to the composition taught by the combined teachings of McCleary and Davis to provide the claimed composition for enhanced mental function.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claim-designated ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daragan et al. (U), Sakai et al. (C*), Gao et al. (N), Ikeguchi et al. (B*) and Singh et al. (Singh, H. K. et al. Indian Journal of Pharmacology, 1997; 29: S359-S365. Neuropsychopharmacological effects of the Ayurvedic nootropic *Bacopa monniera* Linn. (Brahmi)) in view of Davis et al. (U).

Applicant's claimed invention of Claims 1, 2, 4 -7 was set forth above. Applicant further claims the composition of claim 4 wherein the mineral complex comprises magnesium, manganese, potassium, vanadium and zinc. Applicant further claims the composition of claim 5 wherein the magnesium, calcium, zinc and iron are present as Krebs Cycle Intermediates.

Daragan beneficially teaches a composition comprising vitamin A, vitamin E, thiamine chloride (B1), riboflavin (B2), pyridoxine hydrochloride (B6), folic acid (Bc), cyanocobalamin (B12), nicotinamide (PP), ascorbic acid (C), rutin (P), manganese sulfate pentahydrate (MnSO4.5H2O), copper sulfate pentahydrate (CuSO4.5H2O), zinc sulfate (ZnSO4), lipoic and succinic acids, vitamin D, pantothenate (B3), moslecitin, iron sulfate heptahydrate (FeSO4.7H2O), cobalt sulfate heptahydrate (CoSO4.7H2O), potassium iodide (KJ), calcium hydrogen phosphate dihydrate (CaHPO4.2H2O) and magnesium hydrogen phosphate trihydrate (MgHPO4.3H2O), which provides maintenance of high level of physical and mental working ability.

Sakai beneficially teaches a composition comprising phosphatidyl-L-serine having the effect of improving memory impairment.

Gao beneficially teaches a composition comprising docoshexenoid acid (DH) and dimethylaminoethanol (DMAE) which is useful for memory enhancement.

Ikeguchi teaches a composition comprising 2-pyrroidone-5-carboxylic acid (also known in the art as L-pyroglutamic acid) useful in the treatment of mental disorders, such as dementia and amnesia.

Singh beneficially teaches an ethanolic extract from *Bacopa monniera* augmented cognitive function and mental retention capacity.

The combined teachings of Daragan, Ikeguchi, Gao, Ikeguchi and Singh, as set forth above, teach the claimed composition except for wherein the vitamin B12 constituent as vitamin B12 on ion exchange resin.

Davis teaches that serum levels of vitamin B12 are elevated more effectively by oral vitamin bound to an ion-exchange than by free vitamin because the resin-bound form prevents degradation of the drug in the stomach. Thus, it was known in the art at the time of the invention that vitamin B12 on ion exchange resin was an effective vehicle for increased absorption of oral vitamin B12. Therefore, an artisan of ordinary skill would have had a reasonable expectation that using the resin-bound vitamin B12 of Davis in the making of the composition taught by the combined references would be a success. This reasonable expectation of success would have motivated the artisan to provide the vitamin B12 disclosed in the composition taught by the combined references as a resin-bound vitamin B12 as disclosed by Davis because to do so would ensure that the best possibility for enhanced absorption and increased circulation in the blood of vitamin B12.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the claim-designated ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
June 21, 2009

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Primary Examiner, Art Unit 1655